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January 4, 2001

MERCK
Research Laboratories

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: [Docket No. 00D-1562] Draft Guidance for Industry on Cancer Drug and Biological Products—Clinical Data in Marketing Applications

Merck & Co., Inc, is a leading worldwide, human health product company. Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the important pharmaceutical products on the market, today.

Merck's product portfolio is diverse and includes products which are indicated for use within the patient population intended to be most affected by this *Draft Guidance for Industry on Cancer Drug and Biological Products—Clinical Data in Marketing Applications* (hereafter referred to as *The Draft Guidance*). We, therefore, are qualified by this experience to comment on *The Draft Guidance.*

In the course of bringing research candidates through oncology clinical trials, Merck's physicians would rely on guidance such as this for advice on how best to collect, format, analyze and present clinical data for review by FDA's Centers.[1] It is with that perspective in mind, that Merck's oncology team has reviewed *The Draft Guidance* and finds it generally well thought-out advice, that is investigator-friendly and reasonable for the purpose intended.

We understand that *The Draft Guidance* will provide a general framework for the evaluation of all critical data collected on oncology trials within the context of current medical practice. However, our experience in registration of product applications indicates that no amount of guidance on the format and content of applications can substitute for the essential dialogue that must take place between applicants and regulators, particularly when the intended patient condition is life-threatening. Therefore, we recommend that *The Draft Guidance* would be improved by some discussion about the need for, and FDA's support for a continuous dialogue between sponsors and regulators to ensure efficiency and concurrence throughout a development program where there may be a smaller margin for error than usual.

Sincerely,

Dennis M. Erb

Dennis M. Erb, Ph.D.
Senior Director
Regulatory Affairs

[1] Centers = Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER)

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